International Conference on Harmonization (ICH)
M2 EWG Meeting - Summary
San Diego, 05 November - 08 November 2000

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The tasks accomplished and the decisions agreed are the following, whereby present preferences are defined in the current economical and technological reality and do not preclude further development.

Regional information
- Module 1
    - all regions will issue guidance on the electronic submission of module 1
    - will follow standards of the eCTD specification as applicable to the other modules
- Modules 2-5
    - regions will issue guidance on the electronic submission of modules 2-5 as required
    - will follow standards of the eCTD specification as applicable to the other modules

Style Sheets and "web ready
- The eCTD object should be navigable through an XML enabled web browser
- The style sheet(s) should be very basic navigation to any leaf object
    - This view should aid validation processes
    - Review functionality through this view will be very limited
- eCTD object style sheet will be part of eCTD specification/guidance
- Reference point for industry and agency to discuss fileability

File naming
- Case: sensitive
- Length: 32 (including the dot)
- Character set: A-Z a-z 0-9 - _
- Extension: **one** extension, no restriction to number of digits
- Format: directory names fixed, filenames free for applicant to choose

File types

The present preferences are defined in the current economical and technological reality and do not preclude further development.

- Backbone: XML
- Structured data: XML
- Narratives:
    - PDF is acceptable for all narratives in all regions

- o XML is accepted as an optional format for a region when there is a regional definition, but PDF remains acceptable in that region
- o For Overall Summaries (and possibly other summaries) specific regional guidance may require RTF or XLS files to be submitted in addition (to support regional review processes) (restricted to Module 2 only)
- o Change control process will be used to formally include regional developments
- Graphics:
  - o whenever possible use PDF
  - o when better resolution is required, use JPEG, GIF, PNG
  - o special formats for very high resolution may be needed on a case by case basis
  - o When regionally agreed other formats such as TIFF may be used and the other formats remain acceptable

Folder (Directory) hierarchy

- The highest level should identify the submission and aspects of the lifecycle (– to be defined by lifecycle group)
- Folders (sub-directories) should be created which follow the hierarchy of the Table of Contents of the submission. The hierarchy should be followed to a level where a reasonable number of files exist within a single folder (eg. 20 – 30 files).
- There should be no empty folders. Such parts of the hierarchy can be deleted.
- The naming of the folders (directories) should be consistent with the numbering used in the Table of Contents of the CTD.

Life cycle information requirements for any given application

- A Unique Identifier for each specific submission
- The unique identifier is associated with specific information
- What is the submission?
  - Original submission?
  - Subsequent submission?
    - o What original submission is it related to?
    - o How is it related to that submission?
- What does the submission do?
  - Add
  - Replace
  - Nullify [cross-out]

Directory structure described in narrative form or by "screen shots"

- Whenever appropriate, screen shots should be used in our documents

An interim meeting of the EWG was suggested to be held from February 5-8, 2001.